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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,716	03/30/2001	David A. Edwards	2685.1003-008	7248

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ELMOR CRAIG, P. C.  
209 MAIN STREET  
NO. CHELMSFORD, MA 01863

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/822,716

Applicant(s)

EDWARDS ET AL.

Examiner

Mina Haghighatian

Art Unit

1616

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.


Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-8, 13-29 and 49-52.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: Initialed IDS filed 09/20/04.

Continuation of 5. does NOT place the application in condition for allowance because: The amendments and arguments do not place the Application in condition for allowance, because all the limitations of the instant claims are met by the cited prior art references. Specifically, Applicant's arguments regarding Jensen are not persuasive for the following reason. The claims are drawn to a "method of delivery" comprising administration of a multivalent metal cation complexed with a therapeutic agent and a carrier, in a dry powder form. Jensen is disclosing all of the said limitations. Applicant's arguments regarding the "spray dried" particles are still not persuasive because spray drying is a method of making the particles, and not the method of delivery. The "dry powders" made are delivered to the respiratory tract, whether by precipitation or spray drying methods. Spray-dried powders fall under "product-by-process" for examination purposes. Furthermore Maa et al is disclosing spray-dried particles of Insulin reciting the limitations of tap density and particle size. What is missing in Maa et al is the addition of the multivalent metal cation. Jensen is disclosing insulin complexed with zinc.... It is also noted that section "c)" reads "optionally" which implies that all the limitations following the term "optionally" are OPTIONAL limitations. Applicant argues that the rejection of claims 18-20, 29 and 41-43 over Jensen in view of International Ingredient Dictionary and Handbook is not proper because Jensen does not teach the tap density and particle size. However, 1) This was the issue in the first Office Action (Non-final), and was clearly, a typographical error which was corrected in the Final Office Action, the action applicant is responding to. Thus the argument is moot. 2) As mentioned above, the said limitations are under OPTIONAL limitations and Jensen did not have to meet them. Thus the argument is not persuasive and no claim is allowable.

  
GARY KINZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600